ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Faslodex 250 mg/5 ml solution for injection.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One pre-filled syringe contains 250 mg fulvestrant in 5 ml solution.
For excipients, see 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Clear, colourless to yellow, viscous liquid.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Faslodex is indicated for the treatment of postmenopausal women with oestrogen receptor positive, locally advanced or metastatic breast cancer for disease relapse on or after adjuvant antioestrogen therapy or disease progression on therapy with an antioestrogen.

4.2 Posology and method of administration

Adult females (including the elderly):
The recommended dose is 250 mg at intervals of 1 month.

Children and adolescents:
Faslodex is not recommended for use in children or adolescents, as safety and efficacy have not been established in this age group.

Patients with renal impairment:
No dose adjustments are recommended for patients with mild to moderate renal impairment (creatinine clearance ≥ 30 ml/min). Safety and efficacy have not been evaluated in patients with severe renal impairment (creatinine clearance < 30 ml/min) (see 4.4).

Patients with hepatic impairment:
Use Faslodex with caution in treating patients with mild to moderate hepatic impairment. Safety and efficacy have not been evaluated in patients with hepatic impairment (see 4.3, 4.4 and 5.2).

Method of administration:
Administer intramuscularly slowly into the buttock. For full administration instructions see 6.6.

4.3 Contraindications

Faslodex is contraindicated in:
- patients with known hypersensitivity to the active substance or to any of the excipients
- pregnancy and in breast-feeding (see 4.6)
- severe hepatic impairment

4.4 Special warnings and special precautions for use

Use Faslodex with caution in patients with mild to moderate, hepatic impairment (see 4.2, 4.3 and 5.2).

Use Faslodex with caution in patients with severe renal impairment (creatinine clearance less than 30 ml/min) (see 5.2).

Due to the route of administration, use Faslodex with caution if treating patients with bleeding diatheses, thrombocytopenia or those taking anticoagulant treatment.

Thromboembolic events are commonly observed in women with advanced breast cancer and have been observed in clinical trials (see 4.8). This should be taken into consideration when prescribing Faslodex to patients at risk.

There are no long-term data on the effect of fulvestrant on bone. Due to the mode of action of fulvestrant, there is a potential risk of osteoporosis.

4.5 Interaction with other medicinal products and other forms of interaction

A clinical interaction study with midazolam demonstrated that fulvestrant does not inhibit CYP 3A4.

Clinical interaction studies with rifampicin (inducer of CYP 3A4) and ketoconazole (inhibitor of CYP 3A4) showed no clinically relevant change in fulvestrant clearance. Dosage adjustment is therefore not necessary in patients who are co-prescribed fulvestrant and CYP 3A4 inhibitors or inducers.

4.6 Pregnancy and lactation

Faslodex is contraindicated in pregnancy (see 4.3). Fulvestrant has been shown to cross the placenta after single intramuscular doses in rat and rabbit. Studies in animals have shown reproductive toxicity including an increased incidence of foetal abnormalities and deaths (see 5.3). If pregnancy occurs while taking Faslodex the patient must be informed of the potential hazard to the foetus and potential risk for loss of pregnancy.

Fulvestrant is excreted in milk in lactating rats. It is not known whether fulvestrant is excreted in human milk. Considering the potential for serious adverse reactions due to fulvestrant in breast-fed infants, breast-feeding is contraindicated (see 4.3).

4.7 Effects on ability to drive and use machines

Faslodex has no or negligible influence on the ability to drive or use machines. However, during treatment with Faslodex, asthenia has been reported. Therefore caution must be observed by those patients who experience this symptom when driving or operating machinery.

4.8 Undesirable effects

Approximately 47% of patients experienced adverse reactions in the clinical trial programme. However, only 0.9% of patients stopped therapy because of an adverse reaction. The most commonly reported adverse reactions are hot flushes, nausea, and injection site reactions.
The adverse reactions are summarised as follows:

Body System/ Frequency	Very Common (>1/10)	Common (>1/100, <1/10)	Uncommon >1/1000, <1/100
Cardiovascular	• Hot flushes		
Gastrointestinal		• Gastrointestinal disturbance including nausea, vomiting, diarrhoea and anorexia.	
Hepatobiliary disorders		• Elevated liver enzymes, the vast majority <2xULN	
Reproductive and breast			• Vaginal haemorrhage • Vaginal moniliasis • Leukorrhea
Skin		• Rash	• Hypersensitivity reactions, including angioedema and urticaria
Urogenital		• Urinary tract infections	
Vascular		• Venous thromboembolism	
Whole body		• Injection site reactions including transient pain and inflammation in 7% of patients (1% of injections) when given as a single 5 ml injection. • Headache • Asthenia • Back pain	

4.9 Overdose

There is no human experience of overdosage. Animal studies suggest that no effects other than those related directly or indirectly to anti-oestrogenic activity were evident with higher doses of fulvestrant. If overdose occurs, manage symptomatically.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: anti-oestrogen, ATC code: L02BA03

Fulvestrant is an oestrogen receptor antagonist and binds to oestrogen receptors in a competitive manner with an affinity comparable with that of oestradiol. Fulvestrant blocks the trophic actions of

oestrogens without itself having any partial agonist (oestrogen-like) activity. The mode of action is associated with down-regulation of oestrogen receptor (ER) protein.
Clinical trials in postmenopausal women with primary breast cancer have shown that fulvestrant significantly down-regulates ER protein in ER positive tumours compared with placebo. There was also a significant decrease in progesterone receptor expression consistent with a lack of intrinsic oestrogen agonist effects.

Effects on advanced breast cancer
Two Phase III clinical trials were completed in a total of 851 postmenopausal women with advanced breast cancer who had disease recurrence on or after adjuvant endocrine therapy or progression following endocrine therapy for advanced disease. 77% of the study population had oestrogen receptor positive breast cancer. These trials compared the safety and efficacy of monthly administration of 250 mg fulvestrant with a third-generation aromatase inhibitor, anastrozole, at a daily dose of 1 mg.

Overall, fulvestrant at the 250 mg monthly dose was at least as effective as anastrozole in terms of time to progression, objective response, and time to death. There were no statistically significant differences in any of these endpoints between the two treatment groups. Time to progression was the primary endpoint. Combined analysis of both trials showed that 83% of patients who received fulvestrant progressed, compared with 85% of patients who received anastrozole. The hazard ratio of fulvestrant to anastrozole for time to progression was 0.95 (95% CI 0.82 to 1.10). The objective response rate for fulvestrant was 19.2% compared with 16.5% for anastrozole. The median time to death was 27.4 months for patients treated with fulvestrant and 27.6 months for patients treated with anastrozole. The hazard ratio of fulvestrant to anastrozole for time to death was 1.01 (95% CI 0.86 to 1.19). Analysis of results by ER status showed that the use of fulvestrant should be restricted to patients with ER positive breast cancer.

Effects on the postmenopausal endometrium
Preclinical data suggest that fulvestrant will not have a stimulatory effect on the postmenopausal endometrium. A 2-week study in healthy postmenopausal volunteers showed that compared to placebo, pre-treatment with 250 mg fulvestrant resulted in significantly reduced stimulation of the postmenopausal endometrium, as judged by ultrasound measurement of endometrium thickness, in volunteers treated with 20 micrograms per day ethinyl oestradiol.

There are no data on the long-term effects of fulvestrant on the postmenopausal endometrium. No data are available regarding endometrial morphology.

In two studies with premenopausal patients with benign gynaecologic disease, no significant differences in endometrial thickness were observed (measured with ultrasound) between fulvestrant and placebo. However, the duration of treatment was short (1, and 12 weeks, respectively).

Effects on bone
There are no long-term data on the effect of fulvestrant on bone.

5.2 Pharmacokinetic properties

Absorption:
After administration of Faslodex long-acting intramuscular injection, fulvestrant is slowly absorbed and maximum plasma concentrations are reached after about 7 days. Absorption continues for over one month and monthly administration results in an approximate 2-fold accumulation. Steady-state levels are reached after about 6 doses during monthly injections with the major part of the accumulation achieved after 3-4 doses. The terminal half-life is governed by the absorption rate and was estimated to be 50 days. At steady state, fulvestrant plasma concentrations are maintained within a relatively narrow range with approximately 2- to 3-fold difference between maximum and trough concentrations.

After intramuscular administration, the exposure is approximately dose proportional in the dose range 50 to 250 mg.

Distribution:
Fulvestrant is subject to extensive and rapid distribution. The apparent volume of distribution at steady state is large (approximately 3 to 5 l/kg), which suggests that the compound distribution is largely extravascular. Fulvestrant is highly (99%) bound to plasma proteins. Very low density lipoprotein (VLDL), low density lipoprotein (LDL), and high density lipoprotein (HDL) fractions are the major binding components. Therefore no drug interaction studies were conducted on competitive protein binding. The role of sex hormone-binding globulin has not been determined.

Metabolism:
The metabolism of fulvestrant has not been fully evaluated, but involves combinations of a number of possible biotransformation pathways analogous to those of endogenous steroids (includes 17-ketone, sulphone, 3-sulphate, 3- and 17-glucuronide metabolites). Identified metabolites are either less active or exhibit similar activity to fulvestrant in anti-oestrogen models. Studies using human liver preparations and recombinant human enzymes indicate that CYP 3A4 is the only P450 isoenzyme involved in the oxidation of fulvestrant, however non-P450 routes appear to be more predominant *in vivo*. *In vitro* data suggest that fulvestrant does not inhibit CYP450 isoenzymes.

Elimination:
Fulvestrant is eliminated mainly by metabolism. The major route of excretion is via the faeces with less than 1% being excreted in the urine. Fulvestrant has a high clearance, 11±1.7 ml/min/kg, suggesting a high hepatic extraction ratio.

Special populations:
In a population pharmacokinetic analysis of data from Phase III studies, no difference in fulvestrant pharmacokinetic profile was detected with regard to age (range 33 to 89 years), weight (40-127 kg) or race.

Renal impairment
Mild to moderate impairment of renal function did not influence the pharmacokinetics of fulvestrant to any clinically relevant extent.

Hepatic impairment
The pharmacokinetics of fulvestrant have not been studied in patients with hepatic impairment.

5.3 Preclinical safety data

The acute toxicity of fulvestrant is low.

Faslodex and other formulations of fulvestrant were well tolerated in animal species used in multiple dose studies. Local reactions, including myositis and granulomatoma at the injection site were attributed to the vehicle but the severity of myositis in rabbits increased with fulvestrant, compared to the saline control. In toxicity studies with multiple intramuscular doses of fulvestrant in rats and dogs, the anti-oestrogenic activity of fulvestrant was responsible for most of the effects seen, particularly in the female reproductive system, but also in other organs sensitive to hormones in both sexes.

In dog studies following oral and intravenous administration, effects on the cardiovascular system (slight elevations of the S-T segment of the ECG [oral], and sinus arrest in one dog [intravenous]) were seen. These occurred at exposure levels higher than in patients (C_{max} >40 times) and are likely to be of limited significance for human safety at the clinical dose.

Fulvestrant showed no genotoxic potential.
Fulvestrant showed effects upon reproduction and embryo/foetal development consistent with its anti-oestrogenic activity, at doses similar to the clinical dose. In rats a reversible reduction in female fertility and embryonic survival, dystocia and an increased incidence of foetal abnormalities including

tarsal flexure were observed. Rabbits given fulvestrant failed to maintain pregnancy. Increases in placental weight and post-implantation loss of foetuses were seen. There was an increased incidence of foetal variations in rabbits (backwards displacement of the pelvic girdle and 27 pre-sacral vertebrae).

A two-year oncogenicity study in rats (intramuscular administration of Faslodex) showed increased incidence of ovarian benign granulosa cell tumours in female rats at the high dose, 10 mg/rat/15 days and an increased incidence of testicular Leydig cell tumours in males. Induction of such tumours is consistent with pharmacology-related endocrine feedback alterations. These findings are not of clinical relevance for the use of fulvestrant in postmenopausal women with advanced breast cancer.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol 96%
Benzyl alcohol
Benzyl benzoate
Castor oil

6.2 Incompatibilities

In the absence of incompatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

4 years

6.4 Special precautions for storage

Store at 2°C-8°C (in a refrigerator)
Store in the original package in order to protect from light.

6.5 Nature and contents of container

One 5 ml clear neutral glass (Type 1) pre-filled syringe with polystyrene plunger rod. The syringe has a nominal content of 5 ml solution and is fitted with a tamper evident closure.
A safety needle (SafetyGlide) for connection to the barrel is also provided.

6.6 Instructions for use and handling and disposal

Remove glass syringe barrel from tray and check that it is not damaged.
Peel open the safety needle (SafetyGlide) outer packaging. (For safety needle instructions see below).
Break the seal of the white plastic cover on the syringe Luer connector to remove the cover with the attached rubber tip cap (see Figure 1). Twist to lock the needle to the Luer connector.
Remove needle sheath.
Parenteral solutions must be inspected visually for particulate matter and discolouration prior to administration.
Remove excess gas from the syringe (a small gas bubble may remain). Administer intramuscularly slowly into the buttock.
Immediately activate needle protection device upon withdrawal of the needle from patient by pushing lever arm completely forward until needle tip is fully covered (see Figure 2).

Visually confirm that the lever arm has fully advanced and the needle tip is covered. If unable to activate the safety needle, discard immediately into an approved sharps collector.

SafetyGlide Information from Becton Dickinson

WARNING: - Do not autoclave safety needle before use. Hands must remain behind the needle at all times during use and disposal.

Directions for Use of safety needle

Peel apart packaging of the safety needle, break the seal of the white plastic cover on the syringe Luer connector and attach the safety needle to the Luer Lock of the syringe by twisting.

Transport filled syringe to point of administration.

Pull shield straight off needle to avoid damaging needle point.

Administer injection following package instruction.
For user convenience, the needle 'bevel up' position is orientated to the lever arm, as shown in Figure 3.

Immediately activate needle protection device upon withdrawal from patient by pushing lever arm completely forward until needle tip is fully covered (Figure 2).

Visually confirm that the lever arm has fully advanced and the needle tip is covered. If unable to activate, discard immediately into an approved sharps collector.

Activation of the protective mechanism may cause minimal splatter of fluid that may remain on the needle after injection.

For greatest safety, use a one-handed technique and activate away from self and others.

After single use, discard in an approved sharps collector in accordance with applicable regulations and institutional policy.

Figure 1

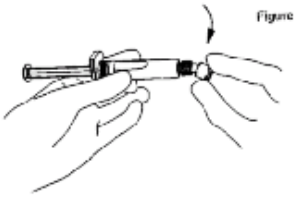
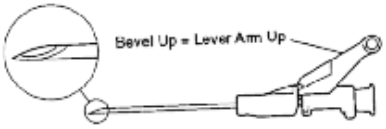


Figure 2

Activated after use

Figure 3



7. MARKETING AUTHORISATION HOLDER

AstraZeneca UK Limited
Alderley Park
Macclesfield
Cheshire
SK10 4TG
United Kingdom

8. MARKETING AUTHORISATION NUMBER(S)

EU/1/03/269/001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 March 2004

10. DATE OF REVISION OF THE TEXT

ANNEX II

A. MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OF THE MARKETING AUTHORISATION

A MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

AstraZeneca UK Limited
Silk Road Business Park,
Macclesfield, SK10 2NA
United Kingdom

B CONDITIONS OF THE MARKETING AUTHORISATION

- **CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IMPOSED ON THE MARKETING AUTHORISATION HOLDER**

Medicinal product subject to medical prescription

- **OTHER CONDITIONS**

The holder of this marketing authorisation must inform the European Commission about the marketing plans for the medicinal product authorised by this decision.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING

CARTON

1. NAME OF THE MEDICINAL PRODUCT

Faslodex 250 mg/5 ml solution for injection.
fulvestrant

2. STATEMENT OF ACTIVE SUBSTANCE(S)

One pre-filled syringe contains 250 mg of fulvestrant in 5 ml solution

3. LIST OF EXCIPIENTS

Ethanol 96%
Benzyl alcohol
Benzyl benzoate
Castor Oil

4. PHARMACEUTICAL FORM AND CONTENTS

1x5 ml. Solution for Injection in a pre-filled syringe.

This pack contains a safety needle (SafetyGlide).

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use. For single use only.

Read the package leaflet before use.

For full instructions on the administration of Faslodex and the use of the safety needle see enclosed Summary of Product Characteristics

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store at 2°C – 8°C (in a refrigerator), in the original package to protect from light.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

AstraZeneca UK Limited
Alderley Park
Macclesfield
Cheshire
SK10 4TG
United Kingdom

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/03/269/001

13. MANUFACTURER'S BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL LABEL

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Faslodex 250 mg/5 ml solution for injection
fulvestrant
IM

2. METHOD OF ADMINISTRATION

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

5 ml

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, nurse or pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

Faslodex ingredients and manufacturer

Faslodex 250 mg/5 ml solution for injection.
Fulvestrant

The active substance is fulvestrant. Each pre-filled syringe (5 ml) contains 250 mg of fulvestrant.

The other ingredients are ethanol 96%, benzyl alcohol, benzyl benzoate and castor oil.

Name of Marketing Authorisation Holder:

AstraZeneca UK Limited
Alderley Park
Macclesfield
Cheshire
SK10 4TG
United Kingdom

Name of the Manufacturer:

AstraZeneca UK Limited
Silk Road Business Park
Macclesfield
Cheshire
SK10 2NA
United Kingdom

What is Faslodex and what it is used for

Faslodex is used to treat breast cancer only in women who have been through the menopause.

Faslodex is a medicine that blocks some of the actions of the female sex hormone, oestrogen, within the body. Oestrogen is involved in maintaining the growth of organs such as the breast, uterus and bone. Oestrogen is linked to the growth of breast cancer.

Faslodex comes in a container with a syringe that is filled and ready for injection into the muscle of the buttock. Each packaging contains a needle for injection.

Before you use Faslodex

Do not have Faslodex:
- If you know you are allergic to fulvestrant or to any of the ingredients in Faslodex.
- If you are pregnant or breast-feeding
- If you have severe liver problems

Take special care with Faslodex:
Tell your doctor if you have any of these medical conditions:
- If you have any problems with your kidneys or your liver.
- If you have a low blood platelet count, a bleeding disorder or if you use anticoagulants (medicine to prevent blood clots).
- If you have had any problems with blood clots
- If you have had any problems with loss of the mineral contents of the bones (osteoporosis)

Pregnancy and Breast-feeding
Do not use Faslodex if you are pregnant or breast-feeding.

Driving and using machines:
Faslodex is not expected to affect your ability to drive or use machines, however you may feel tired after treatment with Faslodex. If this happens to you, do not drive or use machines**.**

Taking other medicines:
Tell your doctor, nurse or pharmacist if you are taking or have recently taken any other medicines - even those you have bought without a prescription. This is important as using more than one medicine at the same time can strengthen or weaken the effect of the medicines. Your doctor may need to take special care or change the dose.

How Faslodex is given

Your doctor or nurse will give you the Faslodex injection. It will be injected slowly into the muscle in your buttock.

The usual dose is:
- one injection given once a month.

Possible side effects

Like all medicines, Faslodex can have side effects. Do not be alarmed by this list of possible effects. You may not have any of them, but tell your doctor as soon as possible if any of the following side effects bothers you or continues:

Very common effects (more than 10 of every 100 patients have these):

- Hot flushes

Common effects (1 to 10 of every 100 patients have these):

- Injection site reactions, such as pain and/or inflammation
- Headache
- Weakness and tiredness
- Gastro-intestinal symptoms (symptoms from the stomach or the bowels), such as nausea (feeling sick), vomiting (being sick), diarrhoea or loss of appetite
- Rash
- Urinary tract infections
- Back pain
- Increased risk of blood clots
- Changes of the levels of the liver enzymes (seen when a blood test is taken)

Uncommon (less than 1 of every 100 patients have these):

- Allergic reactions, including swelling
- Vaginal bleeding
- Vaginal thrush
- Vaginal discharge

Other effects
If you notice any other side effect not mentioned in this leaflet, please tell your doctor, nurse or pharmacist as soon as possible.

Storing Faslodex

Keep out of the reach and sight of children.
Store at $2^{O}C – 8^{O}C$ (in a refrigerator).
Keep Faslodex in the original pack, in order to protect from light.
Do not use after the expiry date on the carton or syringe label.

Your doctor or hospital will normally keep Faslodex for you. The medical staff are responsible for the correct storage, use and disposal of Faslodex.

Further Information
For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

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Tel: +46 8 553 26 000

This leaflet was last approved on {date}

The following information is intended for medical or healthcare professionals only:

Faslodex 250 mg/5 ml solution for injection. Pre-filled syringe.

Instructions for use

Remove glass syringe barrel from tray and check that it is not damaged.
Peel open the safety needle (SafetyGlide) outer packaging. (For safety needle instructions see below).
Break the seal of the white plastic cover on the syringe Luer connector to remove the cover with the attached rubber tip cap (see Figure 1). Twist to lock the needle to the Luer connector.
Remove needle sheath.
Parenteral solutions must be inspected visually for particulate matter and discolouration prior to administration.
Remove excess gas from the syringe (a small gas bubble may remain). Administer intramuscularly slowly into the buttock.
Immediately activate needle protection device upon withdrawal of the needle from patient by pushing lever arm completely forward until needle tip is fully covered (see Figure 2).

Visually confirm that the lever arm has fully advanced and the needle tip is covered. If unable to activate the safety needle, discard immediately into an approved sharps collector.

SafetyGlide Information from Becton Dickinson

WARNING: - Do not autoclave safety needle before use. Hands must remain behind the needle at all times during use and disposal.

Directions for Use of safety needle

Peel apart packaging of the safety needle, break the seal of the white plastic cover on the syringe Luer connector and attach the safety needle to the Luer Lock of the syringe by twisting.

Transport filled syringe to point of administration.

Pull shield straight off needle to avoid damaging needle point.

Administer injection following package instruction.
For user convenience, the needle 'bevel up' position is orientated to the lever arm, as shown in Figure 3.

Immediately activate needle protection device upon withdrawal from patient by pushing lever arm completely forward until needle tip is fully covered (Figure 2).

Visually confirm that the lever arm has fully advanced and the needle tip is covered. If unable to activate, discard immediately into an approved sharps collector.

Activation of the protective mechanism may cause minimal splatter of fluid that may remain on the needle after injection.

For greatest safety, use a one-handed technique and activate away from self and others.

After single use, discard in an approved sharps collector in accordance with applicable regulations and institutional policy.

Figure 1

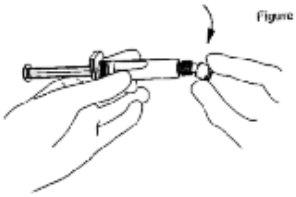

Figure 2

Activated after use

Figure 3